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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,419	08/08/2001	Jamie Rossjohn	3991/OJ678	9005

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EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,419	ROSSJOHN ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/29/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 10-35* is/are pending in the application.

4a) Of the above claim(s) *12-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/27/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6, 8, and 10-35 are pending n the instant application (4/29/05). Claims 7, 9 have been canceled (4/29/05). New claims 31-35 have been added in the amendment filed 4/29/05.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-11, and the IL-3 receptor species) on 3/30/05 is acknowledged. The traversal is on the ground(s) that the restriction is improper because Group I (drawn to a cytokine-binding domain) and Group II (drawn to a method of identifying a cytokine-binding domain) should be grouped together. Applicants request rejoinder of the subject matter of Groups I and II (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995)), in which a new, unobvious material is used in a known process. Ochiai determined that a process was free of the prior art if it employed a product which was free of the prior art. However, only if the product claims of Group I are found allowable, the subject matter of Group I will be rejoined with the process claims of Group II, if the process claims are of the same scope as the allowable product claims.

The Groups as delineated in the restriction requirement (9/30/04) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Therefore, it is suggested that the title be amended to recite the cytokine-binding domain of the specific receptors being examined

Claim rejections-35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1, lines4-6, recites "comprising a region defined by an N-terminus of Domain 4 and by a B'-C' loop" which language is new matter in the claim, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

In the specification pages 2, 3, 4, 5, discloses:

"More preferably, the domain comprises a portion of the B'-C' loop of domain 4 and a groove which is defined by the B'-C', F'-G' loops and the N-terminal section of domain 4 or an analogous structure".

The specification does not disclose the specific limitations recited in amended claim 1. This rejection can only be obviated by reciting the specific limitations for which there are support in the instant specification.

4. Claims 1-6, 8, 10-11, 32-35, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth the specific residues 338-438 of D4β_c which residues were expressed using the pEC611 vector in *E. coli* and that an antibody BION-1 MoAb raised against D4β_c was used to obtain crystals of the antibody and D4β_c. This is insufficient description to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The specification provides no sequence data to allow one to characterize whether the cytokine-binding domain recited in claims 1-6, 8, 10-11 and 32-35 of the elected IL-3 receptor is from human, mouse or other species. No guidance is provided to enable a skilled artisan to predict where in the different species of IL-3 receptor the Tyr421 residue or any of the other residues recited in the claims would be present. Additionally species homologues often display low sequence identity so that identification based solely on sequence similarity is impossible. Under such common circumstances, then it is impossible to identify species homologues. For example in The Cytokine Facts Book (1994), Robin Callard and Andy Gearing. Academic Press Inc. San Diego, CA, the human IL-3 receptor β-chain from human is 897 amino acids compared to the mouse IL-3 receptor β-chain's which are 878 and 896 amino acids (pages 49-51). Based

solely on sequence, it would be clearly impossible for one skilled in the art to identify, for example, the position of the corresponding Tyr421 in mouse because the amino acid corresponding to Tyr421 in human IL-3 receptor β-chain is not the same amino acid at position 421 in the mouse IL-3 receptor β-chain.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The instant specification does not provide an adequate description of the genus of the protein molecules encompassed by these claims. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:
"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606. The instant specification does not provide a structural formula, which is definitive of a genus of human calcium sensitive potassium channel 92 proteins and the DNA encoding such proteins. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentech, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

Thus, the structure of the cytokine-binding domain being claimed is not described in the instant specification. The skilled artisan cannot envision the detailed structure of the

encompassed domain molecules and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Claim Rejections - 35 USC § 112, second paragraph

5. Claims 1-6, 8, 10-11, 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 4, 6, 32-35 are vague and indefinite because there is no SEQ ID NO recited in the claims. Therefore, with respect to the specific amino acids recited, for example the recitation of Tyr365, His367, Ile368, in claim 1, in the absence of a specific reference amino acid sequence or baseline sequence, it is impossible to determine where these specific amino acids are in the cytokine receptors. Similarly with respect to claim 2, it is unclear which sequence the residues 418 and 421 are in. Recitation of these residues in the claim are meaningless in the absence of a reference amino acid sequence.

Claim 3 is vague and indefinite because it recites "a tyrosine residue". However, it is unclear where this tyrosine residue is located in a baseline or reference amino acid sequence.

Claims 1, 3, 6, are vague and indefinite because they recite "including". Regarding these claim, the phrase "including" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 10 is vague and indefinite because it recites "β_c chain is derived from a receptor". It is unclear how much like the receptor the β_c chain is. Is it 80% similar, 50% similar or even 20% similar to the receptor the β_c chain is derived from.

Claim 32 is vague and indefinite because of the recitation of "having" residues is unclear. Does this mean that only each of these residues Ile338, Ala341, Met361 and Tyr365 form the hydrophobic patch of an unclear reference or baseline amino acid sequence? Furthermore, the metes and bounds of the term "hydrophobic patch" are unclear.

Claim 33 is vague and indefinite because it is an improperly dependent claim and is dependent on claim 31, which is a method claim.

Similarly, claim 34 is vague and indefinite because it is an improperly dependent claim and is dependent on claim 31, which is a method claim.

Similarly, claim 35 is vague and indefinite because it is an improperly dependent claim and is dependent on claim 13, which is a method claim.

Despite the improper dependence, the Examiner has examined claims 33-35 as being dependent on claim 1. Appropriate correction is requested by Applicants.

Claims 5, 8, 10-11 are rejected as vague and indefinite insofar as they depend on the above claims for their limitations.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 1-6, 8, 9, 10-11, 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/07215.

The reference discloses an isolated βc chain particularly Domain 4 of the βc chain of the IL-3 receptor (β4 Domain) which binds to at least one cytokine selected from GM-CSF, IL-3 and IL-5 (see page 1, lines 15-35; page 4, last 3 lines; page 5, line 1). The reference also discloses that antibodies were raised by immunizing with fragments of the β4 Domain (see page 31, Example 5, lines 16-24). Furthermore, short peptides of the β4 Domain were also isolated (see page 31, Example 7, lines 34-38).

The disclosure in the reference meets the limitations of the instant claims because the reference discloses an isolated cytokine-binding domain of a βc chain of human IL-3 receptor. Claim 1, line 4, recites "comprising a region" which recitation encompasses the entire βc chain. Furthermore, the absence of the recitation of an amino acid sequence with respect to the recited residues and in the absence of a specific cytokine-binding domain of specific amino acid residues defined in the claims, the reference anticipates the claims because the metes and bounds of the cytokine-binding domain being claimed are unclear.

6b. Claims 1-6, 8, 9, 10-11, 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodcock et al (1997).

The reference discloses using specific antibodies which immunoprecipitate the βc chain of the IL-3 receptor (β4 Domain) which binds to at least one cytokine selected from GM-CSF, IL-3 and IL-5 and for affinity purification of the βc region (see abstract; page 3005, column 2, 6-11; page 3006, column 2, the paragraph disclosing "antibodies").

The disclosure in the reference meets the limitations of the instant claims because the reference discloses an isolated cytokine-binding domain of a βc chain of human IL-3 receptor. Claim 1, line 4, recites "comprising a region" which recitation encompasses the entire βc chain. Furthermore, the absence of the recitation of an amino acid sequence with respect to the recited residues and in the absence of a specific cytokine-binding domain of specific amino acid residues defined in the claims, the reference anticipates the claims because the metes and bounds of the cytokine-binding domain being claimed are unclear.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
May 10, 2005